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UNITED STATES PATENT & TRADEMARK OFFICE

	Examiner: C. A. Azpuru	Group: 1615
Re:	Application of:	Anand R. BAICHWAL, et al.
	Serial No.:	10/047,060
	Filed:	January 14, 2002
	For:	**CONTROLLED RELEASE INSUFFLATION CARRIER FOR MEDICAMENTS**

RESPONSE

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 28, 2003

S i r:

In response to the Office Action mailed February 26, 2003, applicants request reconsideration of the above-identified application in view of the following remarks.

Status of the Claims

Claims 26 - 43 are pending.

I. Rejections under 35 U.S.C. § 112, First Paragraph

In his Final Office Action of February 26, 2003 the Examiner again rejected claims 26 - 43 under 35 U.S.C. § 112, first paragraph, "*as based on a disclosure which is not enabling.*"

The present claims are enabled pursuant to 35 U.S.C. § 112 as explained below. The Examiner's rejection should be withdrawn.

A. The 35 U.S.C. § 112, first paragraph test: Undue Experimentation:

35 U.S.C. § 112, first paragraph states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As explained in detail below, the Examiner has not established that any experimentation is required to practice the invention of the present claims. The novel composition is clearly set forth. The elements of the device are also clearly set out and Applicants have provided specific devices in the specification that are appropriate for practicing the present invention including: (1) the Bespak device, (2) the Priestly device, (3) the Struve device, (4) the Wetterlin device, (5) the device described in GB patent application 2,041,763, (6) the device described in EP 0079478, (7) the Kirk device, (8) the commercially available Easyhaler™, (9) the device described in U.S. Patent No. 5,176,132, (10) the device described in PCT/EP93/01157 and (11) the Miat Cyclohaler™, (hereafter collectively referred to as "the disclosed devices"). Applicants note that the Miat Cyclohaler™ was even used in Example 4 described in the specification. Applicants have cited to the patent documents that describe these devices in detail, and have even disclosed operative commercially available products. One skilled in the art need only put the claimed composition into one of the disclosed devices.

1. Claim 43 is enabled under 35 U.S.C. § 112, first paragraph

Independent claim 43 is a means plus function claim which recites:

> 43. A device for delivering a medicament to a patient, comprising
> a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> means for delivering the cohesive composite to a nasal or oral orafice.

35 U.S.C. § 112, sixth paragraph sets forth the statutory language for means plus function claims and states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

With respect to claim 43, the element in question is any one of the disclosed devices. This element is expressed as a means for performing a specified function (i.e., means for delivering the cohesive composite to a nasal or oral orafice). As statutorily authorized by 35 U.S.C. § 112, sixth paragraph, no recital of structure, material or acts in support of performing the function is given in the claim. The result of using this claim language and invoking 35 U.S.C. § 112, sixth paragraph is that the claim shall be construed to cover the corresponding structure, material or acts described in the specification, (i.e., the disclosed devices).

Thus, Applicants are statutorily authorized to claim their invention in the means plus function format set forth in claim 43. The composition and the disclosed devices are described in detail in the specification on pages 19 - 25. Moreover, commercially available operative devices including the Easyhaler™ and Cyclohaler™ are disclosed. Therefore, under 35 U.S.C. § 112, sixth paragraph, the invention of claim 43, including the claimed novel composition and the means for delivering the composition to the nasal or oral orafice (thoroughly described in the specification as well as numerous patents incorporated by reference in the present specification) is enabled. The Examiner has not cited a single reason for why he considers the invention of claim 43 to be inoperative.

In support of his lack of enablement argument under § 112 first paragraph, the Examiner "reminded" Applicants that "the pharmaceutical formulation does not further limit the claimed device" on page 6 of the Final Office Action.[1] In turn, Applicants remind the Examiner that this point is irrelevant to any rejection of a claim under a 35 U.S.C. § 112 first paragraph enablement analysis, much less a means plus function claim which is statutorily authorized under 35 U.S.C. § 112, sixth paragraph. A finding of lack of enablement requires a finding that there is insufficient

[1]Although the Examiner has made previous, similar statements under 35 U.S.C. § 112 and § 102(b), he has yet to provide any authority for this arbitrary and misguided belief.

disclosure to practice an invention without undue experimentation. Again, the Examiner has not established that any experimentation is needed to practice claim 43.

As the Examiner still has not acknowledged that the specification clearly explains and therefore completely enables the invention of claim 43, Applicants again find it imperative to point out that exemplary medicament delivery devices are described in the specification at pages 19 - 25 and 27 - 29 of the present specification. For purposes of enablement, WO 92/00771, (hereinafter the '771 reference, disclosing the Bespak device), U.S. Patent No. 2,587,215 (hereinafter the '215 reference, disclosing the Priestly device) and U.S. Patent No. 4,274,403 (hereinafter the '403 reference, disclosing the Struve device), provide a more than adequate description of three examples of the disclosed devices. Indeed, the description is well beyond the Examiner's assertion of merely a basic output port, chamber and actuator. Likewise, Applicants find it again necessary to set forth the relevant portions of the specification discussing the references that disclose three examples of the disclosed devices including the '771, '215 and '403 references which are incorporated by reference in Applicants' specification and discussed in its Amendment of January 30, 2003.

The Bespak device is discussed as follows:

> [o]ne such device is known as the Bespak device described in PCT publication WO 92/00771, hereby incorporated by reference, and available from Innovata Biomed Limited. The device described therein includes a storage chamber for storing a powdered drug to be administered and a metering member having metering cups in which individual doses of the powdered drug are placed. Air is inhaled through an inhalation passage at one end of the device and directed into contact with the metering cup that has been filled with the powdered drug. The metering cup is oriented upwardly open to face the air stream and to enable the powder to be released from the cup. Upon inhalation, the dose is mixed with the air flow and continues through the mouthpiece to be inhaled.
>
> The metering cups on the metering member are arranged on an outer frusto-conical wall so that each metering cup is positionable to be upwardly open and face the air flow during inhalation. The metering member rotates so that the metering cups move between a position in which the cup receives a dose of the powered drug from the storage chamber to a position in which the cup is exposed to

> the air flow. As one cup is exposed to the air flow, another cup is aligned with the storage chamber and is being filled with powder. After the dose is blown from the metering cup, and upon subsequent rotation of the metering member, the cup is wiped and cleaned by a wiping element to remove any undispersed powder and then dried via a moisture absorbent material.

The Bespak device is described in even greater detail in the '771 reference. Applicants specifically point the Examiner to pages 3 - 13 and Figures 1 through 8b of the '771 reference. Applicants also point out that this device is clearly an inhalation device and that the "composition" contained therein is discussed in no greater detail than as "a substance in finely divided form" (page 3, line 16) or "a drug in the form of micronised powder" (page 8, line 28).

At page 21 of the specification, the Priestly device is detailed as follows:

> [a]nother device for delivery of inhalation powders is described in U.S. Pat. No. 2,587,215 (Priestly), hereby incorporated by reference. Priestly describes an inhaler having a storage chamber containing a powdered medicament, a mixing chamber and means to move a set dose of medicament from the storage chamber to the mixing chamber. The dose is mixed with air in the mixing chamber and inhaled through a mouthpiece.

In the '215 reference virtually the entire specification is devoted to description of this device, as are all sixteen Figures. The "composition" contained within this inhaler is described in no greater detail than "the powder carrying parts of this embodiment", (see column 5, line 48) or "the powder to be inhaled", (column 2, line 48).

At pages 21 - 22 of the present specification, the Struve device is specifically discussed as follows:

> [y]et another inhalation device suitable for delivering powdered inhalation drugs is described in U.S. Pat. No. 4,274,403 (Struve), hereby incorporated by reference. Struve describes an inhaler for administering a powdered drug nasally, which includes storage means for containing a quantity of the drug therein. The storage means includes a feed hole through which the powdered drug may be received from the storage means. The device further includes a dispensing head operatively coupled to the storage means for

> dispensing the powdered drug more nasally. The dispensing head of the Struve inhaler includes a nozzle, a body portion, a dispensing cylinder and a vent means. The nozzle is shaped to be received in the nasal passage of the user. The nozzle includes a dispensing passageway for dispensing the dose into the nasal cavity of patient.
>
> The body portion is located adjacent the nozzle and has a traverse bore therein. The traverse bore operatively connects the dispensing passageway in the nozzle with the feed hole leading to the drug storage means. The feed hole and the dispensing passageway are transversely offset relative to one another at the points where they enter the transverse bore.
>
> The dispensing cylinder includes a metering chamber. The metering chamber may be selectively aligned with either the feed hole or the dispensing passageway. The dispensing cylinder is slidably received in the transverse bore for movement between a first transverse position in which the metering chamber is aligned with the feed hole and a second transverse position in which the metering chamber is aligned with the dispensing passageway. In its first position, the metering chamber can be filled with a charge of the powdered drug when the inhaler is manipulated. In the second position, places the charge of the powdered drug into the dispensing passageway for inhalation by the user.
>
> The vent means is formed as part of the dispensing cylinder and is capable of venting the metering chamber to atmosphere only in the second position of the cylinder, i.e. when the powder disposed in the device such that it may be inhaled by the user.

In the '403 reference, the Struve device is set forth in six Figures and is described across the entire specification. In the '403 reference, the "composition" is "a powdered medication or drug". The '403 reference further states that "[t]he type of drug being administered is not important to the [Struve] invention and may comprise any drug which is desirably administered to the nasal passages" (column 2, lines 63 - 66).

The composition of the present invention is described in the specification at page 7, line 22 through page 19, line 25, and page 25, line 34 through page 27, line 24.

Finally, the specification describes the combination of the novel composition and any one

of the disclosed devices at page 19, line 27 through page 20, line 6 and the combination of the novel composition and the commercially available Miat Cyclohaler™ in Example 4 beginning on page 27.

In view of pages 7 - 30 of the specification, one of ordinary skill would be enabled to make, use or practice the invention of means plus function claim 43. Therefore, the Examiner is requested to withdraw his rejection of this claim.

2. Claim 26 is enabled under 35 U.S.C. § 112 first paragraph

Independent claim 26 recites:

> 26. A device for delivering a medicament to a patient, comprising
> an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;
> a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

As with claim 43, claim 26 clearly is enabled by the specification. Claim 26 clearly sets forth the novel composition. It also clearly sets forth a device. Numerous examples of the disclosed devices can be found in specification, as discussed above, including commercially available inhalers (e.g. the Easyhaler™ and the Cyclohaler™) and patent documents describing the disclosed devices, (e.g., the '771, '215 and '403 references disclosing the Bespak, Priestly and Struve devices). The Examiner has not established that any experimentation whatsoever is required by one of skill in the art to perform this claim. To the contrary, one need only put the composition in the device and actuate it. As such, claim 26 and the claims dependent thereon are clearly enabled under § 112, first paragraph, and the Examiner's rejection should be withdrawn.

a. The Wands Test regarding Undue Experimentation is misapplied here

In an attempt to bolster his argument in the Final Office Action, the Examiner cited to In re Wands, 8 U.S.P.Q. 2d 1400, (Fed. Cir. 1988). Specifically, the eight "Wands factors" were

applied (or more accurately, misapplied) to determine whether undue experimentation was needed to perform the claimed invention.

It is clear from In Re Wands that the eight Wands factors are applied to determine whether one of skill would be required to perform an undue amount of experimentation. There simply is no reason to apply the Wands factors to the present facts.

Notwithstanding the above, and purely for clarity and arguments sake, Applicants discuss the Wands factors below.

Factor 1 - Nature of the Invention

The present invention is a novel composition contained within a conventional inhaler.

The Examiner argues that the "nature of the invention" deals only with claim limitations directed to the device, specifically an actuator coupled to a chamber, and an output port and does not include the composition limitations. Clearly, this is incorrect. However, a device having an actuator coupled to a chamber and an output port clearly is enabled by the specification and does not require any experimentation, as the Easyhaler™ and the Cyclohaler™ are commercially available.

Factor 2 - State of the Art

The art at issue are devices that store and deliver the particular claimed pharmaceutical composition. The devices of the present invention are well known, and indeed, the Easyhaler™ and the Cyclohaler™ are even commercially available. No experimentation at all is needed to make them. The novel composition and method of preparing it are clearly described in the specification

The Examiner offers a peremptory conclusion that "there are any number of devices which meet these broad limitations." The Examiner is correct that any number of devices meet the device limitations. Indeed, a number of prior art devices, i.e. the disclosed devices, are discussed in the specification of the present application. If the Examiner means to reject the claims as overbroad in view of prior art, he should do so, rather than torture the enablement statute to shoehorn his rejection in.

Factor 3 - Relative skill in the art

As admitted by the Examiner, the level of skill in the art is high. Notwithstanding, the invention is simple and Applicants provide precise instructions on how to practice it. The Examiner's assertion that a highly skilled practitioner would not be able to select one device from the claimed invention as written is ludicrous.

Factor 4 - Predictability in the art

Any one of the disclosed devices will work in the present invention. The invention comprises a conventional inhaler containing a novel composition fully disclosed in the specification. The test for enablement is whether one can make and use the invention without undue experimentation in view of the specification. The Examiner provided no evidence that any experimentation is needed.

In his evaluation of Factor 4, the Examiner specifically complained that more than one invention would meet the criteria of the claims and that one of ordinary skill would not be able to predict with certainty which device is being claimed. Again, the Examiner appears to shoehorn in an enablement rejection, when in reality he is complaining that the claims are overly broad. A proper rejection would be under 35 U.S.C. § 102(b) in view of prior art, not enablement under 35 U.S.C. § 112, first paragraph.

Factor 5 - Breadth of claims

The claims describe a conventional inhaler containing a novel composition.

Here, the Examiner makes clear his complaint that the claims are "quite broad" and that "any device with an output port, a chamber, and an actuator would meet the limitations of the device claims." However, the Examiner completely ignores the fact that the purpose for the "Breadth of Claims" factor is for determining whether the invention requires undue experimentation. The Examiner has not established that any experimentation is required to perform the invention of Claim 26 and therefore, for purposes of an enablement evaluation, the claims are not overly broad.

Factor 6 - Amount of direction or guidance presented

The specification teaches one of skill in the art precisely what to do. The disclosed devices are set forth. The novel composition and how to prepare it are also provided. To practice an embodiment of the invention, one of skill would be taught to:

1) obtain any one of the disclosed devices, including the commercially available Easyhaler™ or Cyclohaler™;
2) manufacture the composition as disclosed;
3) combine the composition with any of the disclosed devices and administer.

The device of Applicants' claims can encompass a number of different devices previously described in the art. This is clearly explained in the specification and a great amount of guidance is given in this regard. What distinguishes the prior art from the present claims is the specific composition stored and delivered by the device. A great deal of guidance is given regarding this composition. (e.g., See Specification at page 7, line 22 through page 19 line 25; and page 25, line 34 through page 30, line 30.)

Under Factor 6, the Examiner laments that little or no guidance is provided as to how the present claims differ from the cited references, other than that the composition differs. This is irrelevant to the question of whether direction is provided to perform the invention of the present claims. Again, the Examiner has confused enablement (§112, first paragraph) with anticipation (§102 (b)) in view of prior art. The purpose of Factor 6 is to assist in the determination of whether undue experimentation is necessary. The Examiner has not established that any experimentation is necessary to practice the invention. The question of whether the claims are novel and nonobvious over specific art belongs in a rejection under § 102(b) or § 103.

On pages 3 - 4 of the Office Action, the Examiner argued that a device cannot be limited by a composition stored in the device and delivered by the device alleging that "[t]his is tantamount to saying that an empty jar of peanut butter differs from one filled with peanut butter." Applicants respectfully submit that this analogy is misguided. Applicants are saying that while a claim directed to a prior art empty jar on its own is not patentable, a claim directed to a prior art jar in combination with a novel peanut butter composition would unquestionably be patentable.

In further support of the fact that a device can be limited by a composition stored within the device, Applicants submit that there are innumerable patents which claim a prior art object (e.g. a device or capsule), wherein the novel feature is a composition stored therein. For example:

Claim 1 of United States Patent No. 6,030,642 recites:

> 1. An oral pharmaceutical dosage unit formulation for the extended release of clonidine to effect central alpha-adrenergic stimulation over a prolonged period upon administration thereof, wherein the oral dosage unit is a **gelatin capsule** containing a homogeneous powder mixture, the homogenous mixture consisting essentially of:
>
> a. from about 0.025 mg. to about 0.40 mg. clonidine for the treatment of attention deficit hyperactivity disorder;
>
> b. from about 30 to about 70 percent by weight of a high molecular weight, high viscosity cellulose ether; and
>
> c. a therapeutically inert, pharmaceutically acceptable adjunct material, wherein the release period is from about 8 to about 12 hours. *Emphasis added.*

Further, United States Patent No. 5,597,582, issued on January 28, 1997 claims:

> 1. A gelatin capsule comprising a **gelatin shell having enclosed therein** based on the total weight of content of from about 200 to about 2000 mg:
>
> of from about 5 to about 50% w/w of an anticancer compound of the formula ##STR3## wherein X is H; hydrocarbyl (1-4C); hydrocarbyl (1-4C) substituted with OH, NH.sub.2, NHR or NRR; halogen; OH; alkoxy (1-4C); NH.sub.2 ; NHR or NRR; wherein each R is independently selected from lower alkyl (1-4C) and lower acyl (1-4C) and lower alkyl (1-4C) and lower acyl (1-4C) substituted with OH, NH.sub.2, alkyl (1-4C) secondary and dialkyl (1-4C) tertiary amino groups, alkoxy (1-4C) or halogen; and when X is NRR, both R's taken together directly or through a bridge oxygen to form a morpholino ring, pyrrolidino ring or piperidino ring;
>
> n is 0 or 1; and
>
> Y.sup.1 and Y.sup.2 are independently either H; nitro; halogen; hydrocarbyl (1-14C) including cyclic and unsaturated hydrocarbyl, optionally substituted with 1 or 2 substituents selected from the group consisting of halogen, hydroxy, epoxy, alkoxy (1-4C), alkylthio (1-4C), primary amino (NH.sub.2), alkyl (1-4C) secondary amino, dialkyl (1-4C) tertiary amino, dialkyl (1-4C) tertiary amino where the two alkyls are linked together to produce a morpholino, pyrrolidino or piperidino, acyloxy (1-4C), acylamido

(1-4C) and thio analogs thereof, acetylaminoalkyl (1-4C), carboxy, alkoxycarbonyl (1-4C), carbamyl, alkylcarbamyl (1-4C), alkylsulfonyl (1-4C) or alkylphosphonyl (1-4C), wherein the hydrocarbyl can optionally be interrupted by a single ether (--O--) linkage; or wherein Y.sup.1 and Y.sup.2 are independently either morpholino, pyrrolidino, piperidino, NH.sub.2, NHR', NR'R'O(CO)R', NH(CO)R', O(SO)R', or O(POR')R' in which R' is a hydrocarbyl (1-4C) which may be substituted with OH, NH.sub.2, alkyl (1-4C) secondary amino, dialkyl (1-4C) tertiary amino, morpholino, pyrrolidino, piperidino, alkoxy (1-4C), or halogen substituents, or pharmacologically acceptable salt of said compound;

of from about 50 to about 95% w/w of an oily excipient selected from the group consisting of soybean oil and fractionated coconut oil;

of from about 0 to about 30% w/w of viscosity modifier; and

of from about 0 to about 10% w/w of a pharmaceutically acceptable surface active agent. *Emphasis added.*

Both of these claims were issued by the United States Patent and Trademark Office. Both of these claims also recite inventions directed to novel compositions stored within a prior art capsule. Just as a prior art gelatin capsule in combination with a novel formulation is patentable and a prior art jar in combination with a novel peanut butter composition is patentable; a claim reciting the combination of a prior art device in combination with a novel formulation must also be patentable. The Examiner is simply wrong on this issue.

Factor 7 - Presence or absence of working examples

Not only does Example 4 teach the making of the novel composition of the present invention, it also teaches the incorporation of the composition into any one of the disclosed devices. In addition, Example 4 teaches the procedure for determining drug delivery from the compositions of Examples 1 - 3. This procedure entails storing and delivering each composition as described in Examples 1 - 3 into a Miat Cyclohaler™. Subsequent results showing the amount of drug released are provided on pages 29 - 30.

For clarity sake, Example 4 is set forth below.

EXAMPLE 4

IN-VITRO DRUG DELIVERY STUDIES

In this example, the products of Examples 1-3 were studied to determine drug delivery of the respective formulations. The fraction containing 45-63 micron particles for each of the products prepared in Examples 1-3 were placed into size 3 gelatin capsules (20 mg -.2 mg). The 45-63 micron fraction was selected to insure shallow lung penetration. The studies were conducted using a Twin Stage Impinger (TSI) apparatus A as described in British Pharmacopeia, 1993, Vol. II (Appendix XVII C, page A 194), incorporated by reference herein. The TSI and monograph provide a determination of the deposition of a dose

emitted from a pressurized inhaler. According to the monograph, the upper and lower impingement chambers correspond to shallow lung and deep lung regions. Thus, by measuring the amount of active ingredient recovered from each chamber, the artisan can determine the amount of drug delivered to each area which is measured as a percentage of the total dose.

Following the procedures set forth in the British Pharmacopeia, supra, separate TSI analyses were carried out for each product, i.e., Examples 1, 2 and 3. A filled capsule was fitted individually into a **MIAT cyclohaler** containing specially molded mouthpiece to fit the inlet to the TSI. The capsules were pierced in the cyclohaler. At each time period indicated in the tables below, the TSI was activated for 10 seconds at 60 dm.sup.3/minute. The device was then disassembled and the liquid in Stages 1 and 2 of the TSI was analyzed by spectrofluorimetry to determine the amount of drug delivered, (excitation wavelength: 235 nm; emission wavelength: 303 nm; scan speed: fast; excitation slit width: 10 nm; sensitivity: low; emission slit width: 10 nm; excitation start wavelength: 200 nm; emission start wavelength: 250 nm; emission end wavelength: 350 nm; excitation end wavelength: 300 nm).

Disassembling of the TSI and analysis was carried out at the different times shown in the Tables below after firing in order to determine the quantities of drug released into stage 1 and stage 2 liquid at the times shown. The results obtained for each of the formulations of Examples 1-3 is provided below: [*Tables listing test results for Examples 1-3 on pages 29-30 of the specification are omitted.*]

From the foregoing data, it can be seen that the products of Examples 1 and 2 where the drug is associated with a polysaccharide, the amount of drug released at time=0 into both chambers is zero or close to zero and increases over the release periods studied in a controlled manner. In the case of the product of Example 3, in which the drug is only associated with lactose, the total payload of drug available for release is released at time=0 with no significant further drug release after that time period. Therefore, the drug concentration, drug:polysaccharide ratio, and manner of drug loading on the carrier are significant controlling or influencing drug release from the insufflation formulations of the present invention. *Emphasis added.*

In his Office Action, the Examiner asserts that the examples are directed to the composition and that they cannot be looked to for any guidance in defining the claimed device. As seen from Example 4 above, the Examiner has not carefully reviewed the specification, and once again, he is wrong.

Factor 8 - Amount of experimentation necessary in adequately determining the actual device

No experimentation is necessary to determine the device used. It is worth restating that to practice an embodiment of the invention, one of skill would be taught to:

1) obtain any one of the disclosed devices including the commercially available Easyhaler™ or Cyclohaler™;
2) manufacture the composition as disclosed;
3) combine the composition with any of the disclosed devices and administer.

The Examiner asserted that the amount of experimentation necessary in adequately determining the actual device would be extreme, and that beyond the basic output port [actuator] and chamber, one of skill would be guided by the closest prior art, which the Examiner claims is extensive.

How can it be possibly be considered "extreme experimentation" for one skilled in the art to find a commercially available inhaler, manufacture a disclosed composition and combine the two together? Even for one of "low" skill in the art, this work would not approach the threshold of any experimentation, let alone surpass the threshold of undue experimentation. Indeed, appropriate commercially available devices including the Easyhaler™ and Cyclohaler™ are even set out in the specification!

II. Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner again rejected claims 26 - 43 under 35 U.S.C. § 112, second paragraph, "*as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*"

In his rejection, the Examiner does not allege that the elements of independent claims 26 and 43 are unclear. He instead objects that the "*composition limitations do not particularly point out the claimed device.*"

The Examiner has improperly rejected the claims. As pointed out above, claim 43 is a means plus function claim. As also pointed out above, 35 U.S.C. § 112, sixth paragraph states

that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

Thus, claim 43 incorporates statutorily authorized means plus function language. It cannot be indefinite. Applicants respectfully request withdrawal of this rejection.

Claim 26 also is clear and definite. Indeed, the Examiner himself has not in any way indicated that claim 26 is unclear. He merely complained that claim 26 includes a limitation (i.e. the composition) that the Examiner disagrees with. If the Examiner believes the claim to be overly broad, the proper place for his rejection is under 35 U.S.C. § 102(b).

As a proper rejection under 35 U.S.C. § 112, second paragraph has still not been set forth, Applicants respectfully request withdrawal of this rejection. As claims 27 - 42 depend from claim 26, withdrawal of the Examiner's rejection of these claims is also requested.

III. Rejections under 35 U.S.C. § 102 (b)

The Examiner again rejected claims 26 - 43 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,284,133 to Burns, et al., (the Burns patent) and under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,239,993 to Evans et al, (the Evans patent).

In response, Applicants remind the Examiner that a proper rejection under 35 U.S.C. § 102(b) requires that each and every limitation of a claim be found in a prior art reference. See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 U.S.P.Q.2D 1508, 1512 (Fed. Cir. 2001), In re Bond. 910 F. 2d 831, 832 (Fed.Cir. 1990); Lindeman Machinefabrik v. Am Hoist and Derrick. 730 F. 2d 1452, 1458 (Fed. Cir. 1984). Further, the Court of Customs and Patent Appeals in In re Bernhart held that "[i]*f the prior art does not show or suggest the improved element itself, it defies logical reasoning to say that the same prior art suggests the use of that improved element in a combination.*" In re Bernhart, 417 F. 2d. 1395, (1969) at 1402.

The Burns patent and the Evans patent each fail to teach hint or suggest

"a device for delivering a medicament to a patient, comprising an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a

patient; a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter; an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port" as recited in claim 26; or

"*a device for delivering a medicament to a patient, comprising a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter; means for delivering the cohesive composite to a nasal or oral orafice*" as recited in claim 43.

As such claims 26 and 43 are not anticipated under 35 U.S.C. § 102 (b). Dependent claims 27 - 42 are also not anticipated.

The Examiner has obsessively held on to his view that the composition is not a limitation of either means plus function claim 43 or claim 26. Yet, he still cites no support for this contention. In contrast, Applicants have cited case law and even issued patents (see U.S. Patent Nos. 6,030,642 and 5,597,582 discussed above) which show that composition limitations can indeed distinguish the claimed device over the prior art.

Moreover, courts have repeatedly held that a single novel feature added to a known combination is patentable. The Federal Circuit has rejected and found untenable under current patent laws, the holding in Lincoln Engineering Co. v. Stewart, 303 U.S. 545 (1938), that "*the improvement of one part of an old combination gives no right to claim that improvement in combination with other old parts which perform no new function in the combination*". See e.g. Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d 840, (Fed. Cir. 1984) at 845; In re Bernhart, 417 F. 2d. 1395, 1402 (C.C.P.A. 1969) at 1403; and See also M.P.E.P. at § 2173.05(j).

The Examiner is respectfully reminded that the decision in Diamond v. Diehr, 450 U.S. 181 (1981) at 187, held that a prior art machine that performed a new algorithm was considered patentable. This is a clear example of how the element of a claim (i.e., the performed algorithm) which distinguishes the claimed invention from the prior art "thing" (i.e. the computer) need not

be merely an improvement of the "thing" itself. This United States Supreme Court decision requires that all limitations of a claim *"must be considered as a whole"*, and that *"[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."* Diamond v. Diehr, at 188. Indeed, even limitations that are not statutory subject matter under 35 U.S.C. § 101 must be considered for purposes of a prior art rejection. Nevertheless, the Examiner failed to even mention this decision in his final Office Action. Although the Diamond v. Diehr decision was directed to patentable subject matter under 35 U.S.C. § 101, the reasoning in Diamond v. Diehr is applicable to other issues of patentability, including 35 U.S.C. § 102. The court in In re Bernhart also addressed a similar issue with respect to a claim directed to a prior art machine performing a novel algorithm as follows:

> 19. A system for providing a drawing of an object comprising in combination: electronic digital computer means programmed to respond to applied signals (x(e), y(e), z(e)) and a series of groups of signals (x(i), y(i), z(i)) to provide a corresponding series of pairs of output signals (v(i), w(i)) with the relationship between signals (x(i), y(i), z(i)) and (x(e), y(e), z(e)) to the signals (v(i), w(i)) being defined as follows:
>
> [Graphic omitted. See illustration in original.]
>
> where k is a selectable variable; signal means coupled with said computer means and providing said signals (x(i), y(i), z(i)) and (x(e), y(e), z(e)) thereto with said signals (x(i), y(i), z(i)) representing the three dimensional co-ordinates of selected points on the object and with said signals (x(e), y(e), z(e)) representing the three dimensional co-ordinates of the location of the observation point from which the object is seen; and planar plotting means coupled with said computer means and responsive to said signals (v(i), w(i)) to make a drawing of the object.

holding that ". . . *we note that the only apparatus recited is the admittedly old computer and plotting machine and the sole distinction presented therein upon which patentability could be predicted is the identification in the claims of the meaning which certain signals represent to the human mind, or the algorithm which the computer is to solve." Emphasis added.* In re Bernhart, 417 F. 2d. 1395, (1969) at 1398. Similarly, the novel element of the present claims, (i.e. the pharmaceutical formulation) is also the feature that distinguishes the invention from the prior art "thing" (i.e. the device). Although the novel formulation is not an improvement of the device itself, it must be considered in a patentability analysis.

The Examiner argues that the improvements described in Applicants' cited cases Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d. 840, (Fed. Cir. 1984) at 845 and In re Bernhart, 417 F.2d. 1395, (1969) at 1403; and M.P.E.P., 8th Ed., at 2173.05(j) are *"a further limitation of what was being claimed."* This point is irrelevant. The above mentioned case law holds that all limitations of a claim must be considered. Once again, **the Examiner has cited no authority whatsoever to justify ignoring express limitations of the present claims.** Moreover, it is clear from the decisions in In re Bernhart, Diamond v. Diehr and Radio Steel that all claim limitations, even including elements that are not, in and of themselves novel or even statutory subject matter, must be considered for patentability. The Examiner correctly points out that in the present application, Applicant is further limiting a device through the use of pharmaceutical limitations. As the pharmaceutical limitations are proper limitations in the claims and as these limitations are not found in the cited prior art, the claims of the present invention cannot be anticipated by the cited references. Just as a novel algorithm is to a prior art computer and a novel formulation is to a prior art capsule, so is the present novel composition to the prior art device.

For the above reasons, removal of the Examiner's rejection of claims 26-43 under 35 U.S.C. § 102 (b) is respectfully requested.

IV. Conclusion

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if it is determined that any further issues remain.

Respectfully submitted,
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